

THE IMPLEMENTATION OF RAPID HIV TESTING AT PUBLICLY FUNDED COUNSELING AND TESTING SITES IN NEW JERSEY

Eugene Martin, Ph.D. ¹, Sindy M. Paul, M.D., M.P.H. ², Phil Bruccoleri², Franchesca Jackson¹, Karen Stralkus¹, Evan Cadoff, M.D. ¹, Gratian Salaru, M.D. ¹
 UMDNJ – Robert Wood Johnson Medical School¹ and
 New Jersey Department of Health and Human Services ²

Issues/Background

- Efforts by public health authorities to control the spread of HIV in the United States have been frustrated by the inability of providers to provide HIV testing and results in a single client encounter.
- During 2002, approximately 35% of patients visiting NJ Counseling and Testing Sites (CTS) for HIV testing failed to receive their results, largely because they failed to return for a scheduled follow-up visit.
- Recently, the U.S. Food and Drug Administration (FDA) approved the first CLIA 'waived', rapid (fingerstick) HIV point-of-care test for use in the United States (OraQuick® Rapid HIV-1 Antibody test, OraSure Technologies, Inc., Bethlehem, PA). FDA approval included a contingency that mandated a Quality Assurance program be in place before testing is offered.
- In the State of New Jersey, additional state licensure is required for any facility engaged in clinical laboratory testing regardless of CLIA waiver.
- Mandatory Quality Assurance program MUST be in place before offering Oraquick testing.

Aim

Implementation of rapid-testing for HIV in the State of New Jersey by using approved rapid-testing methods.

The OraQuick® Rapid HIV-1 Antibody test

Testing Basics

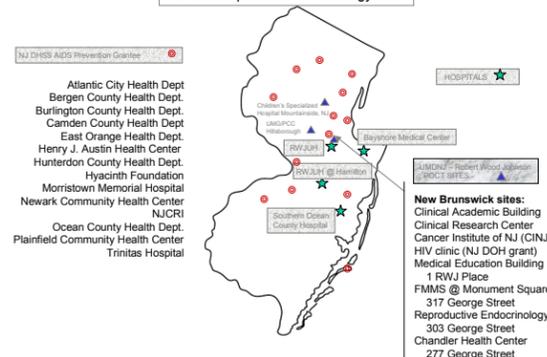
- Perform a fingerstick
- Fill loop in sampling device with blood
- Add to developer solution
- Mix
- Add testing device
- Wait 20 – 40 minutes
- Read



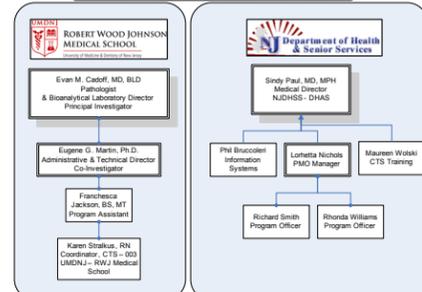
Methods

- Build upon existing UMDNJ-Robert Wood Johnson Medical School, multi-facility, point-of-care-testing program
- Develop a centralized quality assurance process
- A single site in New Brunswick, NJ was used to delineate a process development strategy, validate forms, communications, equipment and techniques.
- Testing began November 2003 at the first NJ licensed site.
- Additional sites were selected to roll out the program.
- Review activities at least monthly
- By June 2004, 16 primary sites and 8 satellite sites including an ER department were offering rapid testing.
- Expansion to approximately 200 satellite facilities is in progress and will be completed in 2005.

RWJMS Department of Pathology Sites



RAPID HIV TESTING IMPLEMENTATION TEAM



Quality Assurance Plan

- Management by a board certified Pathologist
- Supervisory control through site coordinators
- Central lab overseers:
 - Regulatory and proficiency testing
 - Acquisition and validation of supplies
 - Inventory control
 - Common procedures and core policies
 - Uniform administration at all locations
 - Common training, certification of personnel, forms
 - Core communication hub www.njihiv.org
 - Quality Control Rules
 - Standardized monthly site visits – 'The Report Card'
- Intra and inter site comparisons to insure that requirements for quality and process control are maintained

Quality Assurance Issues Encountered:

- Temperature Issues
 - Reagent Storage
 - Storage of Controls
 - Testing Environment
- Reading of Devices
 - Under vs. Over Ascertainment
 - Documentation
- Availability of procedures
- Supervisory Oversight
- Availability of Technical Support

PERFORM QC AT A MINIMUM 1-CELEBRITY-LEVEL. WHENEVER NEW EQUIPMENT ARRIVES, CHECK QC BEFORE TO INSURE THAT ALL PARTICIPANTS QUALITY TESTING BEING IMPLEMENTED CORRECTLY.

FACILITY: East Orange Health Dept. Reagent LOT NUMBER: 0104769
 BOX NUMBER: 1 BOX LOT NUMBER: 0204727 Reagent Kit EXPIRATION DATE: August 2004

DATE	IDENTIFICATION/Reason	ROOM	TEMP	CONTROL	REAGENT	START- END TIME	OPERATOR
1	Positive Control	25	20	Y	POS	10 min	AL
2	Negative Control	25	20	Y	NEG	10 min	AL
3	10000000	25	20	Y	POS	10 min	AL
4	10000000	25	20	Y	NEG	10 min	AL
5	10000000	25	20	Y	POS	10 min	AL
6	10000000	25	20	Y	NEG	10 min	AL
7	10000000	25	20	Y	POS	10 min	AL
8	10000000	25	20	Y	NEG	10 min	AL
9	10000000	25	20	Y	POS	10 min	AL
10	Positive Control	25	20	Y	POS	10 min	AL

Comment (EOMS): It is highly likely that the process of all controls, including a negative control, was not performed. The negative control requires that you mix a lot of controls on the day of the testing each week.

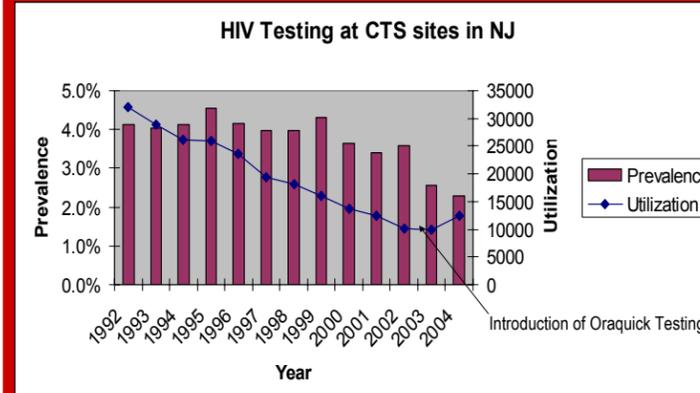
Comment (EOMS): Temperature was not recorded for this control. Temperature should be recorded for each control.

Comment (EOMS): Test Time was a big issue - your water did not dry by your clock. Allow more time for drying.

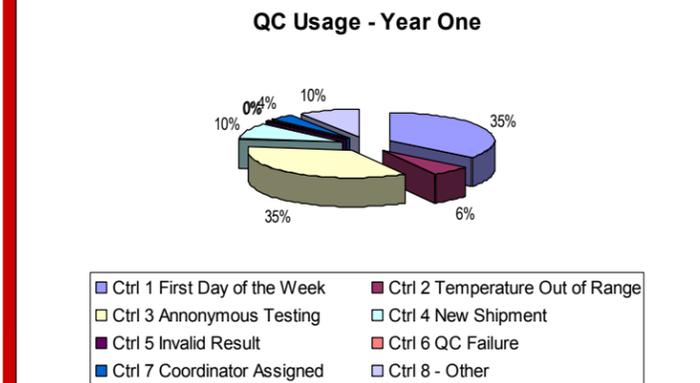
Comment (EOMS): Since your patient identification in specimen ID was in our spreadsheet.

Comment (EOMS): Do not re-use.

Total tests	Results + counseling	HIV +	HIV -
10,601	10,469 (99%)	228 (3%)	10,329 (97%)



A decade-long decline in HIV testing at CTS sites was reversed, with a 25% increase in 2004.



Results

In New Jersey, the ability of satellite sites to start rapid testing is limited by the licensure process. In order to optimize the expansion of services statewide, satellites have been stratified into priority levels based on prevalence and testing volume.

EXPANSION OF SITES:

Fifteen sites have been identified as high volume and prevalence sites. Fourteen more have been identified as second tier in importance based on prevalence and volume. The remaining 129 satellite sites are of lower priority based on prevalence and testing volume and will be implemented as resources permit.

RETURN FOR RESULTS:

Through July 2004, 3062 people had HIV rapid testing, 3053 of whom (99.7%) received their results and had posttest counseling. Out of the 110 confirmed positive results, 69 (63%) were previously undiagnosed patients.

QUALITY CONTROL (QC) RESULTS:

Sites run QC for a variety of reasons. During 2003-4, 19.5% (1925) of devices were used to perform QC. The majority of QC was run as a part of mandated operating procedures. Approximately 6% of QC was run because of 'Out of Temperature Range' findings at monitored storage locations. Mandatory QC due to an invalid result was extremely rare.

FALSE POSITIVE RATE:

The false positive rate was 4.05/10,000. All false positive were Type I discordants i.e., reproducible, OraQuick® Positive, EIA/Western Blot negative. No examples of Type II discordants – evolving infections in a window period.

Conclusion

In New Jersey, the ability to start rapid-testing is limited by licensure process and quality assurance requirements. By use of a standardized, centralized approach rapid testing has been implemented in an efficient, cost-effective and quality-focused process. Low false-positive rates in New Jersey may be due to currently employed methodology and aggressive quality assurance oversight.